

**REMARKS/ARGUMENTS**

Applicant hereby responds to the non-final office action of October 31, 2007. By the foregoing amendment, claims 53, 58, 61 and 63 have been amended to clarify the claimed subject matter. No new matter has been added. Reconsideration is requested.

**35 U.S.C. §102 Rejections**

In the Office Action, independent claims 53 and 61-63 were rejected under 35 U.S.C. §102(e) as being anticipated by United States Patent No. 5,588,960 (Edwards et al.). Applicant again traverses this rejection.

Edwards describes a medical device which includes an elongate probe member sized to enter the female urethra and at least one tubular needle or electrode that is advanceable through the wall of the urethra and useable to suitable agent or medication to tissue surrounding the urethra.

Independent claim 53, as currently amended, recites a system that is useable to guide the advancement of a guidewire from a location within the lumen of a blood vessel to a target location within or outside of the wall of that blood vessel. More specifically the system recited in claim 53 comprises an elongate flexible catheter body that is advanceable through the vasculature into said blood vessel lumen, said catheter body having a side wall and at least one lumen extending longitudinally therethrough, an opening formed in the side wall of said catheter body, a tissue penetrating element that has a lumen and is alternately disposable in a) a first position wherein the tissue penetrating element is substantially within the catheter body and b) a second position wherein the tissue penetrating element assumes a predetermined curved configuration and extends out of the opening formed in the side wall of said catheter body so as to penetrate a wall of the blood vessel adjacent to the blood vessel lumen in which the catheter is positioned and a guidewire that is advanceable through the lumen of the tissue penetrating element while the tissue penetrating element is in the second position. Additionally, claim 53 requires that the system include one or more imageable markers useable in conjunction with an imaging apparatus to facilitate adjustment of the rotational orientation of the catheter body within the blood vessel so that subsequent advancement of the tissue penetrating element will cause the tissue penetrating element to advance in the direction of the target location. Examples of the claimed imageable marker(s) are shown in Figures 4D-4K and 6-6D of the present application. In some embodiments, the

imageable marker(s) is/are imaged by an extracorporeal imaging device such as a fluoroscope. In other embodiments the claimed imageable marker(s) is/are imageable by an imaging apparatus, such as an intravascular ultrasound imaging apparatus, positioned on or in the catheter body. In either event, as explained in Applicant's specification, these imageable marker(s) perform the important function of enabling the operator to adjust the rotational orientation of the catheter body within the blood vessel lumen *before* the tissue penetrating element has actually been advanced to substantially ensure that, when the tissue penetrating element is *subsequently* advanced it will travel in the direction of the intended target and not in some other radial direction.

In contrast to the invention recited in independent claim 53, the system described by Edwards does not describe any guidewire that is advanceable through the tubular needle or electrode. Therefore, for this reason alone, the present claims are not anticipated by Edwards.

Furthermore, Edwards et al. does not describe or even suggest any imageable markers that are useable in conjunction with an imaging apparatus to facilitate adjustment of the rotational orientation of the catheter body within the urethra so that subsequent advancement of his tubular needle or electrode tissue will cause the tubular needle or electrode to advance in the direction of a particular target location. In fact, Edwards does not purport to be capable of advancing a single tubular needle or electrode to some discrete target location situated to one particular side of the urethra. Rather, Edwards describes embodiments that have multiple tubular needles or electrodes that advance in different radial directions such that the desired agent or medication is delivered to tissue surrounding the urethra.

Accordingly, the stated rejection of claims 53 and 61-63 were rejected under 35 U.S.C. §102(e) should be withdrawn.

### 35 U.S.C. §103 Rejections

Also in the Office Action, dependent claims 54-58 were rejected under 35 U.S.C. 103(a) as being obvious over Edwards et al. in view of United States Patent No. 5,464,395 (Faxon et al.).

Faxon et al. describes a catheter for delivering therapeutic and/or diagnostic agents directly into the tissue surrounding a bodily passageway. The catheter comprises at least one

needle cannula able to be projected outboard of the catheter so as to deliver the desired agents to the tissue. The catheter also preferably includes one or more inflatable balloons.

However, like Edwards, et al., Faxon et al. fails to describe or suggest any guidewire that is advanced through his needle cannula to a target location nor does Faxon et al. even remotely suggest any imageable markers that are useable in conjunction with an imaging apparatus to facilitate adjustment of the rotational orientation of his device within the body lumen so that subsequent advancement of his needle cannula will cause the needle cannula advance in the direction of a particular target location. Thus, for at least the same reasons stated above with respect to Edwards (as well as other reasons not specifically articulated here) the claims as presently amended are also patentably distinguishable over the combination of Edwards et al. and Faxon et al.

**Conclusion**

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5484.

Respectfully submitted,

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